

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC.,

Plaintiff,

v.

DAIICHI SANKYO EUROPE GMBH,

Defendant.

Civil Action No. 1:23-cv-02568-ER

**DEFENDANT'S OPPOSITION TO PLAINTIFF'S  
MOTION FOR JUDGMENT ON THE PLEADINGS**

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November 15, 2023

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## INTRODUCTION

This case turns on whether a pharmaceutical clinical trial (the “CLEAR Outcome Study” or “Study”) yielded certain data sufficient to satisfy the relative risk reduction component of the Regulatory Milestone Payment in the Agreement between Defendant Daiichi Sankyo Europe GMBH (“DSE”) and Plaintiff Esperion Therapeutics, Inc. (“Esperion”). If (i) the Study yielded the result that Esperion had powered the Study to achieve and (ii) the European Medicines Agency (“EMA”) ultimately approved an expanded label consistent with the Agreement, DSE agreed to reward Esperion with an additional \$200 or \$300 million dollars (on top of the \$300 million that DSE has already paid Esperion). Unfortunately, the Study data was less than “spectacular,” as the relative risk reduction rate for the Study’s main research question—the “MACE-4” primary endpoint—fell short of the Regulatory Milestone’s 15% threshold, thereby failing to satisfy the first of two requirements needed to trigger the Regulatory Milestone.<sup>1</sup> Esperion claims that the Study’s primary endpoint, the only one that can provide the basis for regulatory approval by EMA, was not the only relative risk reduction rate that could satisfy the 15% threshold, but rather *any* risk reduction rate in the Study, including a host of lesser “secondary” endpoints, could suffice. This is simply fantastical thinking on Esperion’s part.

Esperion sued, seeking a declaratory judgment that its interpretation of the risk reduction component is correct. Esperion later filed the operative First Amended Complaint (“FAC”), which focuses heavily on extrinsic evidence. On June 20, 2023, DSE filed its Answer, explaining why Esperion’s interpretation is wrong and detailing how the FAC misrepresented the extrinsic evidence. DSE’s Answer also explains the significant differences between primary and secondary

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<sup>1</sup> “MACE” stands for Major Adverse Cardiovascular Events. “MACE-4” is a composite endpoint of four different major cardiovascular events. *See infra* page 3–4.

endpoints, how those differences are common knowledge in the pharmaceutical industry, and why, because of these material differences, “[n]o rational pharmaceutical company” would have agreed to pay Esperion hundreds of millions of dollars based on the relative risk reduction rate of any one of several secondary endpoints. Since June, the parties have engaged in extensive discovery on a whirlwind schedule in preparation for an April 2024 trial date. The parties have exchanged over a million pages of documents, served extensive interrogatories and seven third party subpoenas, and are now deposing nearly 20 witnesses in a 35-day window. Esperion also filed two discovery-related letter motions, both of which the Court denied on October 18, 2023.

After pushing for this frenetic schedule, Esperion has suddenly asked for judgment on the pleadings under Rule 12(c), four months after DSE filed its Answer, taking the remarkable position that all of this discovery is for nothing. According to Esperion, it turns out the plain language of the Agreement has always been unambiguously in its favor, such that none of the ample extrinsic evidence in the FAC matters. Rule 12(c) requires Esperion to show, construing the pleadings in the light most favorable to DSE and drawing all reasonable inferences in its favor, that DSE has no *plausible* defense. Esperion does not come close to meeting this high standard.

Construing the pleadings in a light most favorable to DSE and drawing all reasonable inferences in its favor, DSE’s proposed interpretation of the Agreement is reasonable and DSE has far more than a “plausible” defense. *First*, DSE’s position is consistent with the customs and practices of the pharmaceutical industry. The Agreement is governed by New York law, which requires courts to interpret a contract consistent with the relevant customs and practices of the particular trade or business of the parties. Here, the pleadings create a plausible inference that a reasonable reader, cognizant of the customs, practices, usages and terminology of the pharmaceutical industry, would understand that the relative risk reduction component of the

Regulatory Milestone Payment could only be satisfied by the Study’s primary endpoint and main research question. This plausible inference alone defeats the Rule 12(c) motion. *Second*, DSE’s proposed interpretation of the Agreement’s plain language is not unreasonable, which independently defeats Esperion’s motion. The term “the relative risk reduction rate” in Section 9.2 is undefined, but the Agreement’s language and the public version of the Study’s protocol—to which the Agreement provides a link—confirm that only *one* relative risk reduction rate in the Study matters because it lists only the primary endpoint and no secondary endpoints.

In contrast, Esperion’s core argument—that the words “a result” in Section 9.2 refer to any one of a number of outcomes in the Study, including several secondary endpoints—appears nowhere in the FAC. Esperion also ignores that the words “a result” are part of the well-known idiom “as a result of” (which means “because of”), rather than a modified noun referring to one of several secondary results of the Study. Quite frankly, this tortured interpretation is nonsense.

For these reasons, Esperion’s motion for judgment on the pleadings should be denied.<sup>2</sup>

## STATEMENT OF FACTS

### I. ESPERION LAUNCHES THE CLEAR OUTCOME STUDY.

“In 2016, Esperion . . . launched the CLEAR Outcome[] Study.” FAC ¶ 27; Answer ¶ 27. “[A]ccording to the study protocol, the CLEAR Outcome Study was a randomized, double-blind, placebo-controlled study designed to assess if treatment with bempedoic acid versus placebo decreases the risk of cardiovascular events in patients who are statin intolerant.” *Id.* A study “protocol typically includes a primary endpoint that the study is designed to measure.” *Id.* at 2. “The primary endpoint is the most important [measurement] for evaluating the effect of an intervention/treatment.” *Id.* The “primary efficacy endpoint and primary outcome measurement

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<sup>2</sup> While DSE has stuck to the pleadings for purposes of this curiously-timed motion, DSE has uncovered evidence that directly undermines Esperion’s position, which DSE looks forward to presenting to the Court at the appropriate time.

of the CLEAR Outcome Study was MACE-4, a composite of four major adverse cardiovascular events including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, and coronary revascularization.” *Id.* ¶¶ 3, 28.

The Study also included “secondary endpoints in addition to the main, primary MACE-4 endpoint,” such as evaluating all-cause mortality, cardiovascular deaths, and strokes. *Id.* ¶ 28; FAC ¶ 28. “Secondary endpoints serve to provide data that support the primary endpoint, but unlike primary endpoints, they generally cannot on their own result in an approved drug label.” Answer at 3. “These are among the reasons why secondary endpoints are less critical and carry less weight with regulators.” *Id.* “Secondary endpoints may provide additional clinical characterization of treatment effects but are, by themselves, not sufficiently convincing to establish the main evidence in an application for a license or for an additional labeling claim.” *Id.* (quoting U.S. National Institutes of Health, Glossary: National Center for Advancing Translational Sciences Toolkit for Patient Focused Therapy Development, available at <https://tinyurl.com/425m9xjv>).

## **II. THE PARTIES NEGOTIATE AND SIGN THE AGREEMENT.**

On or around November 8, 2018, DSE sent Esperion a Statement of Interest that would grant DSE an exclusive license to develop and commercialize bempedoic acid in certain European countries in exchange for various payments (including a contingent regulatory milestone payment). Answer ¶ 31. Shortly thereafter, the “parties began negotiating and drafting the Agreement.” *Id.* ¶ 35; FAC ¶ 35. On January 2, 2019, Esperion and DSE executed the Agreement. Answer ¶ 43; FAC ¶ 43. Section 9.2 includes the following table describing under what conditions a Regulatory Milestone Payment would be paid to Esperion.

**9.2. Regulatory Milestone Payment.** Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within thirty (30) days following receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	\$200,000,000
Equal to or greater than 20%	\$300,000,000

The Agreement does not define “cardiovascular risk reduction” or “the relative risk reduction rate.” However, “[t]he parties understood and agreed, during negotiations and at the time they executed the Agreement, that the relative risk reduction component of the regulatory milestone was tied to the Study’s MACE-4 primary endpoint and not to any of the secondary endpoints.” Answer ¶ 33. Both parties were aware of the “distinction” between primary and secondary endpoints when they entered the Agreement, and that “[n]o rational pharmaceutical company would have” paid “Esperion \$200-300 million for a 15% or greater relative risk reduction (“RRR”) for a secondary endpoint, which on its own could never have materialized in an approved label.” *Id.* at 3. Indeed, at the time the Agreement was signed, certain “key” secondary endpoints on which Esperion now hangs its hat were neither designated as “key” nor organized in a statistical hierarchy (meaning there was no ranking of these secondary endpoints in relationship to one another). Esperion amended the Study Protocol in September 2020—*well after the Agreement was signed*—to add certain secondary endpoints to the statistical testing hierarchy, thereby allowing risk reduction percentages for those endpoints to be reported as “statistically significant” secondary endpoints. Declaration of Toni-Ann Citera (“Citera Decl.”), Ex. 1 at 10 (Protocol

Amendment 3.1 (July 30, 2018)); Ex. 2 at 11, 249, 264–65 (Protocol Amendment 5).<sup>3</sup> Esperion also re-labeled certain secondary endpoints as “key” secondary endpoints. *Id.*

The Agreement defines the “CLEAR Outcome Study” to mean “the Clinical Study conducted by or on behalf of Esperion pursuant to the protocol entitled ‘A randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant.’” FAC, Ex. 1 at 6 (the “Agreement” at 3). The Agreement also specifically references the CLEAR Outcome Study in two of the Agreements’ Schedules (Schedule 1.60 – Global Clinical Studies and Schedule 2.11 – Global Development Plan). Agreement at 66, 69. Both Schedules include a chart that lists the Study, its specific “Study ID,” “1002-043,” and describes the design of the Study as “assessing the occurrence of MACE.” *Id.* at 66, 69 (the “study assess[es] the occurrence of MACE in patients with, or at high risk for, [Cardiovascular Disease] who are unable to tolerate statin therapy”). The Study Protocol in effect at the time of the Agreement (Amendment 3.1) defined “MACE” as MACE-4.

The Agreement also contains two draft press releases. One states that “Esperion is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, depending on the range of relative risk reduction in the CLEAR Outcomes study.” *Id.* at 74. The other draft press release

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<sup>3</sup> The Court may consider Amendment 5 because it is integral to the pleadings given that they reference the secondary endpoints discussed within it and use specific quotes from that Amendment, such as “key secondary efficacy end points.” *E.g.*, FAC ¶ 28. Amendment 3.1 may be considered by the Court because it is referenced in the pleadings via the Agreement and was the Study Protocol in effect when the Agreement was negotiated and executed, *e.g.*, FAC, Ex. 1 at 6 (referencing the Study’s specific “protocol”); *see also id.* at 69, 72 (referencing the specific study), and because it is otherwise integral to the pleadings given their references to the Protocol.

provides a link to the federal government’s clinicaltrials.gov<sup>4</sup> website listing for the Study, stating the link was last accessed on December 12, 2018. *Id.* at 78–79 (citing <http://clinicaltrials.gov/ct2/show/NCT02993406?term=bempedoic-acid&rank=4>). The listing available on December 12, 2018 (Version 9, submitted November 9, 2018 and posted on November 13), details *one* “primary outcome measure”—MACE-4—and does not list *any* “secondary outcome measures,” even though a field is provided for secondary endpoints. <https://clinicaltrials.gov/study/NCT02993406?tab=history&a=9>. The same is true of Version 10 (submitted on December 12, 2018, and posted on December 13. <https://clinicaltrials.gov/study/NCT02993406?tab=history&a=10>. And of Version 8 (submitted on October 16, 2018 and posted on October 17). <https://clinicaltrials.gov/study/NCT02993406?tab=history&a=8#study-id-card>. Indeed, even to this day, there is only one endpoint listed on clinicaltrials.gov for the Study: the MACE-4 primary endpoint. <https://clinicaltrials.gov/study/NCT02993406#study-plan>.

In addition, the Study Protocol in effect when the Agreement was negotiated and signed (Amendment 3.1) used the phrase “relative risk reduction” approximately twelve times, each time in reference to the MACE-4 primary endpoint, and never in reference to any other endpoint. Citra Decl., Ex. 1 at 9 (Protocol Amendment 3.1 (“This event-driven trial is designed to provide 85% power to detect an approximate 14.3% relative risk reduction in the primary 4-component MACE endpoint . . . .”)); *id.* (“In addition, the trial is designed to provide more than 90% power to detect an approximately 17% relative risk reduction in the primary 4-component MACE endpoint.”); *see*

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<sup>4</sup> “ClinicalTrials.gov is a publicly available website and online database of clinical research studies and information about their results. The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals.” <https://www.clinicaltrials.gov/about-site/about-ctg>.

*also id.* at 74, 125–28. In other words, Amendment 3.1 does not use the phrase “relative risk reduction” in connection with any of the Study’s secondary endpoints, only the **primary** endpoint.

“Esperion’s words and actions . . . after execution of the Agreement . . . confirm that it too understood the RRR component of the Regulatory Milestone Event was tied to the primary endpoint.” Answer at 3. For instance, Esperion “did everything it could **after** signing the Agreement to achieve at least a 15% [RRR] for the MACE-4 primary endpoint, knowing a substantial payout would follow if the study results reached that threshold (and the regulator approved the requisite label set forth in the Agreement).” *Id.* at 3–4.

### **III. THE PRIMARY ENDPOINT OF THE CLEAR OUTCOME STUDY DOES NOT ACHIEVE THE RESULT IT WAS POWERED TO ACHIEVE.**

Although the Study did show a statistically significant risk reduction in its sole primary endpoint (MACE-4), it failed to achieve a 15% or greater risk reduction rate for that endpoint as required under the Agreement. Answer at 5–6. Because of this, on March 14, 2023, DSE informed Esperion that it was not entitled to any Regulatory Milestone Payment under Section 9.2 of the Agreement, “irrespective of any approved label in Europe.” *Id.* at 5. The market also did not react favorably to the Study results. *Id.* at 6. “Esperion’s stock dropped **37.2%** between its disclosure of the study results” on March 4, 2023, and “any public mention of its dispute with DSE,” which occurred on March 15. *Id.* at 5–6, ¶ 81. As one article put it, the Study data was “lacklustre” and the “13% reduction in the risk of cardiovascular events is statistically significant but not spectacular.” Madeline Armstrong, ACC 2023 – Esperion’s Outcomes Win Looks Lacklustre, Evaluate Vantage (March 4, 2023), <https://tinyurl.com/yw2da929> (cited in Answer at 6 n.6).

### **LEGAL STANDARD**

The standard for assessing “a Rule 12(c) motion for judgment on the pleadings is identical to that for granting a Rule 12(b)(6) motion for failure to state a claim,” except that “both plaintiffs

and defendants can move for judgment on the pleadings under Rule 12(c).” *Lively v. WAFRA Investment Advisory Group, Inc.*, 6 F.4th 293, 301, 305 (2d Cir. 2021). In deciding a motion under Rule 12(c), “a court may consider the pleadings, exhibits to the pleadings, statements or documents incorporated by reference in the pleadings, any matter of which the court may take judicial notice, and documents that are ‘integral’ to the complaint.” *Great Am. Ins. Co. v. Houlihan Lawrence, Inc.*, 449 F. Supp. 3d 354, 364 (S.D.N.Y. 2020). The Court cannot credit any allegations in the Complaint that have been denied, because “the question for determination is whether on the undenied facts alleged in the complaint and assuming as true all the material allegations of fact in the answer, the plaintiff is entitled to judgment as a matter of law.” *Allstate Ins. Co. v. Vitality Physicians Group Practice P.C.*, 537 F. Supp. 3d 533, 545 (S.D.N.Y. 2021) (cleaned up).

“Thus, where it is the plaintiff seeking a judgment on the pleadings, he will only prevail if, after drawing all reasonable inferences in favor of the defendant, the defendant has failed to allege facts that would give rise to a plausible defense.” *Perdum v. Forest City Ratner Companies*, 2014 WL 12829216, at \*3 (E.D.N.Y. May 30, 2014) (citing *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 429 (2d Cir. 2011)). Put another way, to prevail under Rule 12(c) the moving party must “establish[] that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law.” *Powermat Techs., Ltd. v. Belkin Int’l Inc.*, 2020 WL 2892385, at \*5 (S.D.N.Y. Apr. 2, 2020) (quoting *Juster Assocs. v. City of Rutland*, 901 F.2d 266, 269 (2d Cir. 1990)).

Under New York law, the initial determination of whether a contract is ambiguous is a matter of law, but if the court finds a contract ambiguous a fact-finder evaluates extrinsic evidence to resolve the ambiguity. “The key inquiry at the initial stage of interpreting a contract is . . . whether it is ambiguous with respect to the issue disputed by the parties.” *Glob. Reinsurance Corp. of Am. v. Century Indem. Co.*, 22 F.4th 83, 94 (2d Cir. 2021) (quotation marks omitted).

“Whether a contract is ambiguous is a question of law subject to [the court’s] de novo review.” *Id.* “[A]n ambiguity exists where the contract could suggest more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement and who is cognizant of the customs, practices, usages and terminology as generally understood in the particular trade or business.” *Id.* (cleaned up). “In determining whether a contract is ambiguous, courts look within the four corners of the document.” *Id.* (cleaned up). “This does not mean, however, that courts may not consider proof of custom and usage to determine ambiguity,” because such proof is objective evidence about what language means, as opposed to inadmissible “extrinsic evidence of the parties’ subjective intentions.” *Id.* If after considering such evidence, “the language in the contract remains ambiguous, then the parties may submit extrinsic evidence as an aid in construction, and the resolution of the ambiguity is for the trier of fact.” *Id.* at 94–95 (cleaned up).

### **ARGUMENT**

The pleadings, construed in DSE’s favor, fail to show that Esperion prevails as a matter of law. Esperion’s only basis for its Rule 12(c) motion is that the contract’s language unambiguously supports its position. But DSE has plausibly alleged at least two reasons why Section 9.2 of the Agreement can be reasonably read as requiring the CLEAR Outcome Study to achieve at least a 15% relative risk reduction for its primary endpoint as a condition of receiving the Regulatory Milestone Payment. Either reason suffices to defeat Esperion’s motion. *First*, DSE has plausibly alleged that, considering pharmaceutical industry custom and practices, a reasonable reader would understand the “relative risk reduction rate” to be referring only to the primary endpoint of “the CLEAR Outcome Study.” *See* Agreement at 37. *Second*, the Agreement’s plain language does not unambiguously state that the risk reduction rate requirement is satisfied by *any* result of the CLEAR Outcome Study, which read in the manner Esperion suggests, could include the primary

endpoint, any one of several secondary endpoints, or other outcomes that are even less important, such as tertiary endpoints. Rather, interpreting “the relative risk reduction rate” as referring to the Study’s primary endpoint (MACE-4) is a reasonable interpretation, given that the term is not defined and textual evidence supports the existence of only a singular risk reduction metric. Esperion’s plain language argument falls flat because it focuses in isolation on the words “a result” in Section 9.2. According to Esperion, these words unambiguously mean that any one of multiple Study results would trigger the milestone payment. But the words “a result” are imbedded within the well-known idiom “as a result of,” which simply means “because of.”

Esperion also makes numerous arguments about allegations DSE has denied, how this litigation has unfolded, and Esperion’s financial position. These arguments provide no support to Esperion’s Rule 12(c) motion and can be safely ignored. However, they do show the disingenuous nature of Esperion’s motion and that, contrary to counsel’s representations to the Court, Esperion was unable to make its argument without resorting to extrinsic evidence such as evidence supposedly showing the litigation is causing Esperion financial harm (Br. 18). *See* Oct. 18, 2023 Hearing Tr., ECF No. 77 at 33:16–24 (“There is no extrinsic evidence required, whatsoever.”).

**I. DSE HAS PLAUSIBLY ALLEGED THAT INDUSTRY CUSTOM AND USAGE SUPPORT ITS INTERPRETATION OF SECTION 9.2.**

The Court must consider the customs and practices of the pharmaceutical industry in assessing whether DSE has alleged a reasonable interpretation of Section 9.2. Under New York law, “contract[s] must be construed according to the custom and use prevailing in a particular trade.” *See Seven Star Shoe Co., Inc. v. Strictly Goodies, Inc.*, 657 F. Supp. 917, 921 (S.D.N.Y. 1987) (quoting *Edison v. Viva Int’l, Ltd.*, 70 A.D.2d 379, 421 N.Y.S.2d 203, 205 (1st Dep’t. 1979)). “Evidence of trade practice and custom may assist a court in determining whether a contract provision is ambiguous in the first instance,” even though it is technically outside the four corners

of the contract. *Sompo Japan Ins. Co. of Am. v. Norfolk S. Ry. Co.*, 762 F.3d 165, 180 (2d Cir. 2014). That is because certain language or terms may “have a specialized meaning in a particular industry.” *Id.* at 180; *see also Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 180 (2d Cir. 2004) (contract term is “ambiguous if it could suggest more than one meaning when viewed objectively, in the context of each . . . agreement and the customs, practices, and usages as generally understood in the [relevant] trade” (cleaned up)).

Despite Esperion’s overheated rhetoric, the parties’ actual disagreement is narrow. Importantly, the parties agree, to quote Esperion, that “[t]he ‘cardiovascular risk reduction’ rate—and the corresponding amount of the milestone payment—is **based on** the results of the CLEAR Outcomes Study,” assuming a certain label is approved in Europe as set forth in the Agreement. FAC ¶ 4 (emphasis added); *see also* Answer ¶ 4; Br. 1, 4. Thus, the term “the relative risk reduction rate”—while undefined in the Agreement—can only be understood in relation to what the CLEAR Outcome Study was actually measuring and on what any approved label will actually be based. This just leaves one “question:” “Does the contract provide that *any one of several cardiovascular risk reduction [rates]* from the study triggers DSE’s payment obligation . . . or is the payment obligation triggered by *only one particular [rate]* . . . ?” Br. 1.

Here, the pleadings present a “plausible inference” that one reasonable interpretation of “the relative risk reduction rate”—taking into account the customs, practices, and usages prevailing in the pharmaceutical industry—is a reference to the relative risk reduction rate of the Study’s primary MACE-4 endpoint. *See Jackson v. Harvest Cap. Credit Corp.*, 2018 WL 2041389, at \*4 (S.D.N.Y. Apr. 30, 2018). As explained in DSE’s pleadings, the *only* reasonable interpretation of the contract is that the Agreement required the primary endpoint of the Study to show a relative risk reduction rate of 15% or greater, given the importance of the primary endpoint

relative to other results. *See* Answer at 1–3. However, as discussed above, the Court need only find DSE has alleged facts creating a plausible inference its proposed interpretation is reasonable in light of industry custom and usage to defeat Esperion’s motion. DSE has done that.

Based on that reasonable interpretation, the Regulatory Milestone Payment is conditioned on the Study showing a MACE-4 relative risk reduction rate of 15% or more. The pleadings explain that “[i]n the pharmaceutical industry, drug sponsors conduct clinical trials” that distinguish between “a primary endpoint” and “non-primary endpoints.” Answer at 2. It is widely recognized in the industry that “primary and secondary endpoints are not created equal, nor are they interchangeable.” *Id.* “The primary endpoint is the most important [measure] for evaluating the effect of an intervention/treatment” and “provides the basis for determining whether the study met its objective.” *Id.* at 2–3 (quotation marks omitted). Secondary endpoints, “unlike primary endpoints . . . generally cannot on their own result in an approved drug label.” *Id.* at 3. For these reasons, “[n]o rational pharmaceutical company would have” “pa[id] Esperion \$200-300 million for a 15% or greater relative risk reduction (“RRR”) for a secondary endpoint, which on its own could never have materialized in an approved label.” *Id.* Thus, the fact that DSE acknowledges the Study had many results does not matter. *See* Br. 2–3. Rather, one can plausibly infer that “the relative risk reduction rate” of a study that triggers a milestone payment of this size will be only the primary endpoint(s) of said study. *See Eternity Global*, 375 F.3d at 180–81 (holding term ambiguous even where dictionary definition suggested a different meaning because definition “does not take into account what [term] means in the context of a particular industry”).

## **II. THE CONTRACT’S PLAIN LANGUAGE DOES NOT UNAMBIGUOUSLY ENTITLE ESPERION TO ITS REQUESTED RELIEF.**

### **A. DSE’s proposed interpretation of Section 9.2’s language is reasonable.**

Industry custom and usage aside, a reasonable interpretation of Section 9.2’s plain

language is that Esperion receives the Regulatory Milestone Payment only if the CLEAR Outcome Study demonstrates at least a 15% “relative risk reduction” for its primary endpoint (MACE-4). In “ascertaining the meaning of contractual language” a court “read[s] the integrated agreement as a whole.” *Glob. Reinsurance*, 22 F.4th at 95 (quotation marks omitted). “In conducting that exercise, words and *phrases* should be given their plain meaning, and the contract should be construed so as to give full meaning and effect to all its provisions.” *Id.* (quotation marks omitted and emphasis added). In determining plain meaning, the “words . . . cannot be taken out of context” but must be read in light of their surroundings. *See SOS Oil Corp. v. Norstar Bank of Long Island*, 563 N.E.2d 258, 262 (N.Y. 1990). As discussed above, the parties agree on how Section 9.2 works as to most issues, and the disagreement turns mainly on whether “the relative risk reduction rate” term refers to the Study’s primary endpoint or any Study cardiovascular risk reduction rate. *Supra* at 12.

DSE’s reasonable interpretation of “the relative risk reduction rate” term is that it refers only to the CLEAR Outcome Study’s one primary endpoint (MACE-4). In addition to the custom and usage discussed above, this interpretation is consistent with other aspects of the Agreement and not contradicted by any language in the Agreement.

For example, the Agreement contains a press release discussing the CLEAR Outcome Study and linking to the Study Record of the CLEAR Outcome Study on ClinicalTrials.gov. Agreement at 79.<sup>5</sup> The Study Record provides in part an “Outcome Measures” section, which consists of two separate spaces: one for primary outcome measures (i.e., primary endpoints) and one for secondary outcome measures (i.e., secondary endpoints). In that section, Esperion lists *a*

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<sup>5</sup> (citing <https://clinicaltrials.gov/ct2/show/NCT02993406?term=bempedoic-acid&rank=4> (last accessed December 12, 2018))

*single outcome measure*: the primary MACE-4 endpoint, in the primary outcome measures space, leaving the secondary outcome measures space blank. Version 9 Study Details, Outcome Measures (Nov. 9, 2018), <https://clinicaltrials.gov/study/NCT02993406?tab=history&a=9>. By the time of Version 9, the Record History (which is also available at the link from the press release) shows Esperion had indeed made revisions to the Outcome Measures section, changing the primary outcome measure from the original MACE-5 to MACE-4 on July 23, 2018 (prior to the Agreement). However, in the twenty-four revisions to the Study Record over an approximate six-year span Esperion made, they never once revised the Study Record to add a secondary outcome measure, even though the law required that Esperion submit to ClinicalTrials.gov all “primary and secondary outcome measures.” See 42 U.S.C. § 282(j)(2)(A)(ii)(II); 42 C.F.R. § 11.28 (“For such applicable clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in . . . 42 U.S.C. § 282(j)(2)(A)(ii).”); 42 C.F.R. § 11.10. Thus, a reasonably intelligent reader of the Agreement would know of only one “relative risk reduction rate” measurement that the Study was measuring: the relative risk reduction rate for MACE-4.

In stark contrast to the apparent lack of urgency that Esperion demonstrated with the long-blank space it left in the Study Record for the Study’s secondary endpoints, Esperion now contends that the Regulatory Milestone Payment is equally as payable on any secondary endpoint (such as the “reduction in non-fatal heart attacks”) as it is on the primary endpoint. Br. 2, 13 n.2. In support of this position, Esperion relies on its assertion that the Agreement is silent on MACE-4, emphasizing that the Agreement does not specifically mention MACE-4. But the Agreement does reference MACE-4, twice: in Schedule 1.60 (Global Clinical Studies) and Schedule 2.1.1 (Global Development Plan). Agreement at 66, 69. Both include a chart that lists pending studies, and in the “Design” column, it describes the CLEAR Outcome Study using the term “MACE,” which the

Study Protocol unequivocally defines as MACE-4. Instead, it is every endpoint other than MACE-4 that the Agreement is silent on. *Compare* FAC ¶ 28, *with* FAC Ex. 1.

Even if, *arguendo*, the Agreement did not reference MACE-4, the Agreement’s language would nevertheless belie Esperion’s interpretation. Esperion provides no broader definition of “risk reduction rate” other than to suggest that it should also cover “secondary efficacy end points” of the Study. In an attempt to bolster its argument, Esperion appears to rely on references to the Study’s secondary endpoints from a post-Agreement Study Protocol amendment, Amendment 5, which spells out as “key” the secondary endpoints. Citera Decl., Ex. 2 at 3–4. Notably, however, those same secondary endpoints that Esperion now claims support a \$200 or \$300 million milestone payment are not identified as “key” or tested sequentially in the Study Protocol *in effect* when the Agreement was signed. *See, e.g.*, Citera Decl., Ex. 1 at 3. And while Protocol Amendment 3.1—the Study Protocol in effect at the time the Agreement was executed—uses the phrase “relative risk reduction” at least a dozen times, every single use is tied to the MACE-4 primary endpoint, never to any secondary endpoint, which unequivocally supports DSE’s position. *Id.* at 9, 74, 125–28.

The Agreement’s text also does not suggest that the CLEAR Outcome Study will produce multiple “relative risk reduction rates,” but instead refers to “*the* relative risk reduction rate indicated below” in Section 9.2 (emphasis added), confirming that *one* relative risk reduction rate mattered for purposes of the milestone payment: the study’s primary endpoint—the most important endpoint and the only outcome measurement listed on clinicaltrials.gov. Esperion’s own authority recognizes that the use of the article “the” before a noun means that the noun is singular. Br. 10 (collecting cases).

Esperion contends that the phrase “the relative risk reduction rate indicated below” only refers to “the specific contractual thresholds of 15% and 20%.” Br. 15. But Section 9.2’s statement that “Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study” is written in the present tense, describing the event that has occurred to trigger the milestone. Thus, if one inserts the percentage obtained in the Study, the relevant language would read “the label that correlates with the relative risk reduction rate [of X%] as a result of the CLEAR Outcome Study,” which still supports the interpretation that only one relative risk reduction rate tied to the CLEAR Outcome Study matters. *See* FAC ¶ 89 (arguing Esperion should receive a \$200 million milestone payment “upon Regulatory Approval that ‘includes cardiovascular risk reduction in the label that correlates with *the relative risk reduction rate*’ that is ‘[e]qual to or greater than 15% and less than 20%’” (emphasis added)). While Esperion downplays the importance of the phrase “the relative risk reduction rate” now, it feared this issue so much that it misleadingly replaced the definite article “the” with the indefinite article “a” in its FAC – a subtle but telling sleight of hand. *See* FAC ¶ 77 (quoting Section 9.2 and referring to “cardiovascular risk reduction in the label that correlates with **[a]** relative risk reduction” (emphasis added)). In any event, Esperion’s argument “the relative risk reduction rate indicated below” only refers to the specific contractual percentages does not provide any support for interpreting “the relative risk reduction rate” to mean multiple rates.

In addition, the only other place in the Agreement that mentions “relative risk reduction” also suggests that the CLEAR Outcome Study would be producing only one rate that mattered. One of the press releases attached to the Agreement states that “Esperion is also eligible to receive a substantial additional regulatory milestone payment . . . depending on *the range of relative risk*

*reduction* in the CLEAR Outcomes study.” Agreement at 74 (emphasis added). Had the “relative risk reduction” term been referring to multiple Study results, the press release would have stated this not as a singular range (i.e., “the range”), but instead as multiple “ranges” in discussing the milestone. But the press release did not, again confirming the milestone was tied to a singular relative risk reduction rate. Thus, the fact the study had multiple results does not mean that any one of them can satisfy this component of the milestone. *Contra* Br. 2–3.

**B. Esperion’s arguments for why the contract is unambiguous based on the pleadings lack merit.**

While DSE’s interpretation is reasonable, Esperion’s argument that the Agreement is unambiguous is not. Tellingly, Esperion’s current argument represents a significant shift from the FAC, which spends most of its energy going through extrinsic evidence in seeming acknowledgement that Section 9.2 is likely ambiguous given the relevant terms are undefined. *See, e.g.*, FAC ¶¶ 11, 29–42. Just as tellingly, the linchpin of Esperion’s unambiguous language argument are the words “a result”—pulled out of context from the phrase “as a result of” found in Section 9.2. *See* Br. 8. But this “a result” argument cannot be found in the FAC at all, and instead is a strained litigation-contrived invention the Court should reject.

**Plain Language.** Esperion’s plain language argument is simple, but deeply flawed. Esperion first argues that “Section 9.2 provides that ‘a result’ of the Study can trigger DSE’s payment obligation.” Br. 8. It next argues that “[t]he ordinary meaning of the indefinite article ‘a’ modifying the noun ‘result’” shows the parties understood “that the Study would yield multiple results reflecting cardiovascular risk reduction” that “could trigger the Payment.” *Id.* at 9. This argument fails at the first step. Although Esperion’s brief devotes three pages to this argument, Esperion does not once acknowledge that Section 9.2 uses the words “a result” as part of the well-known idiom “as a result of.” *Id.* at 8–10. An idiom is “a group of words whose meaning is

different from the meanings of the individual words,” such as how “[l]et the cat out of the bag” means “to tell a secret by mistake.” Oxford Learner’s Dictionaries, <https://tinyurl.com/59f4nf8z>. The word “result” is not used in Section 9.2 to refer to one of several Study results that could trigger the milestone, but as part of an idiom (“as a result of”) to mean “because of.” Thus, an ordinary reader of the English language would understand Section 9.2 as saying that “the relative risk reduction rate” that qualifies Esperion in part for the Regulatory Milestone Payment must be *because of* [i.e., “as a result of”] the CLEAR Outcome Study.

Multiple dictionaries confirm this reading.<sup>6</sup> The phrase “as a result of” is used to link another identified result to a prior event or events that caused this result. Cambridge Dictionary defines “as a result of something” as a phrase meaning “because of something,” giving examples such as “She died last week **as a result of** complications from Parkinson’s disease.” Cambridge Dictionary, “as a result of something,” <https://tinyurl.com/3f29ze29> (emphasis added). In the Cambridge Dictionary example, “She died last week” is the result, “as a result of” means “because of,” and the event (*i.e.*, the something) is “complications from Parkinson’s disease.” *Id.* Other dictionaries also define “as a result of” to mean “because of something that has happened.” *See* McGraw-Hill’s Dictionary of American Idioms at 20 (2005), <https://tinyurl.com/yvenr4pm>; Meriam-Webster, “as a result,” <https://tinyurl.com/4ka2ma57>.

In contrast, Esperion’s reading not only ignores the English language as a general matter, but does so selectively, disregarding how the idiom “as a result of” is used in approximately nine other provisions throughout the Agreement, each time clearly taking on its common meaning of “because of.” *See* Agreement at 37 (“Except as otherwise expressly provided in this Agreement,

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<sup>6</sup> “[D]ictionary definitions [are] judicially noticeable facts under Fed. R. Evid. 201(b).” *Page v. Ellenoff Grossman & Schole LLP*, 2023 WL 3606455, at \*1 n.2 (S.D.N.Y. May 24, 2023) (citing *Gen. Star Indem. Co. v. Driven Sports, Inc.*, 80 F. Supp. 3d 442, 446 n.1 (E.D.N.Y. 2015)).

under no circumstances shall a Party, **as a result of** this Agreement, obtain any ownership interest or other right in any Know-How, Patent Rights, or other intellectual property rights of the other Party . . . .”); *see also id.* at 2, 14, 46, 47, 51, 53, 61, 62. And pursuant to the “presumption of consistent usage,” the phrase “as a result of” should be given the same meaning each time it is used in the Agreement. *See GPIF-I Equity Co. v. HDG Mansur Inv. Servs., Inc.*, 2013 WL 3989041, at \*3 (S.D.N.Y. Aug. 1, 2013).

In addition, courts also frequently use the phrase “as a result of” to mean “because of.” A search of Westlaw reveals thousands of examples just within the Second Circuit. *E.g., Sec. & Exch. Comm’n v. Govil*, 2023 WL 7137291, at \*5 (2d Cir. Oct. 31, 2023) (“An investor who suffered no pecuniary harm as a result of the fraud is not a victim.”); *United States v. Gates*, 84 F.4th 496 (2d Cir. 2023) (“Gates does not identify any prejudice that she suffered as a result of the district court’s failure.”); *In re Wythe Berry Fee Owner LLC*, 2023 WL 6486423, at \*6 (Bankr. S.D.N.Y. Oct. 5, 2023) (“As a result of the Debtor’s Chapter 11 case, the Debtor removed this proceeding from State Court . . . .”). In contrast, none of Esperion’s cases support pulling the words “a result” out of the phrase “as a result of” and turning those two words into an article and noun that refer to an actual “result” of the event in the sentence. Instead, they all confirm that use of an “indefinite article ‘a’” before a “noun” in a *non-idiom context* suggests that the noun “is but one of several of that kind.” Br. 10 (quoting *Renz v. Grey Advert., Inc.*, 135 F.3d 217, 222 (2d Cir. 1997), which stated the phrase “‘age was a motivating factor’ . . . suggested that age was one of the considerations motivating the employer’s decision”). But that is irrelevant as the Agreement uses “a result” as part of an idiom.

Esperion cannot avoid the fact that a reasonable reader would interpret “as a result of the CLEAR Outcome Study” to mean “because of” or, as Esperion itself used, “based on” “the

CLEAR Outcome Study,” as opposed to “a result” referring to one of several results of the Study. *See* FAC ¶ 4 (admitting that “[t]he ‘cardiovascular risk reduction’ rate—and the corresponding amount of the milestone payment—is **based on** the results of the CLEAR Outcomes Study” (emphasis added)). Esperion had it right the first time. In addition, Esperion’s own brief slips up and uses this idiom, despite its best attempt not to. Br. 17 (“ . . . Section 9.2 is not ambiguous. As a result, the Court does not need to and should not consider any extrinsic evidence . . .”).

Esperion’s remaining textual arguments are derivative of its flawed “a result” analysis and thus should be disregarded. For instance, Esperion argues that the lack of limiting language around “a result” can be contrasted with limiting language in other parts of the Agreement that refer to results. Br. 10–12 (giving an example of Section 7.2.1 stating “that the parties ‘may publish *certain key results* achieved in connection with this Agreement”). But because “a result” is part of an idiom, it does not need limiting language, because it does not refer to “a result” of the CLEAR Outcome Study at all. Esperion also contends “[t]he parties’ intentional use of the indefinite article ‘a’ is dispositive,” Br. 12, but once again this argument is irrelevant because it concerns text where the article “a” modifies a noun, not text where “a” is part of an idiom.

**Canons of Construction.** Likewise, neither of Esperion’s cited canons support its position.

Esperion tries to rely on the “general terms canon” to rehash its argument for a broad reading of “a result.” Br. 12. But this canon adds nothing. It simply states that “[w]ithout some indication to the contrary, general words (like all words, general or not) are to be accorded their full and fair scope [and] are not to be arbitrarily limited.” *Billard v. Charlotte Cath. High Sch.*, 2021 WL 4037431, at \*20 (W.D.N.C. Sept. 3, 2021) (quoting *Koenke v. Saint Joseph’s Univ.*, 2021 WL 75778, at \*3 (E.D. Pa. Jan. 8, 2021)). But of course, as discussed above, the words “a

result” are found in the phrase “as a result of,” which has a distinct and separate meaning from the broad reading that Esperion seeks to give it. Thus, context gives an extremely strong indication that the words “a result” are not being used in a general manner to refer to results. Esperion’s own authority demonstrates this, as it differentiated between a statute using the term “appeal” without limiting language, thus meaning “appeal” includes “petitions for certiorari,” and statutes “distinguish[ing] between notices of appeal and petitions for certiorari,” which gives appeal a narrower meaning. *United States v. Weiss*, 52 F.4th 546, 553 (3d Cir. 2022).<sup>7</sup>

Esperion also invokes the canon against superfluity to argue that DSE’s interpretation would render superfluous Section 9.2’s provision that “[t]he milestone payment shall be able only once.” Br. 13. Esperion misreads the contract. There are *two* products, Nustendi and Nilemdo, with two separate marketing authorization applications that could potentially receive a qualifying label. Agreement at 68 (listing products). Without the “payable only once” language, approval of each could trigger the milestone (*i.e.*, each would be payable on the first regulatory approval of a Licensed Product in a DSE Territory, if the primary endpoint achieved at least a 15% relative risk reduction). In addition, the DSE Territory definition includes countries outside of the European Union and the jurisdiction of the EU regulator. Without this limitation, approval in the EU and a non-EU country could arguably trigger the milestone multiple times, again, if the primary endpoint met the 15% risk reduction threshold. So the “payable only once” language serves an important role unrelated to the parties’ endpoint dispute. In fact, the “payable only once” language is used in the Commercial Milestone section of the Agreement for these same reasons. *Id.* at 37 (§ 9.3).

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<sup>7</sup> Esperion’s other authority also just concerns the general use of terms without qualifiers or other language indicating a different meaning, unlike here. See *Arizona v. Tohono O’odham Nation*, 818 F.3d 549, 556–57 & n.4 (9th Cir. 2016) (term “land claim” not defined in statute and “[t]he statutory context and surrounding language do not produce much clarity either”); *In re Lehman Bros. Inc.*, 478 B.R. 570, 588–89 (S.D.N.Y. 2012) (“constru[ing] ‘held’ according to its ordinary meaning” given no language in contract suggested a different meaning applied and this construction was also supported “by the principle of contract construction requiring a presumption of consistent usage”).

In contrast, if Esperion’s interpretation is taken at face value such that the Regulatory Milestone Payment would be paid for any endpoint that achieved at least a 15% relative risk reduction rate, but “only once,” it would be unclear of which endpoint the payment would be based on in a scenario where one (or more) was between 15% and 20% and one (or more) was 20% or greater. Would it be the highest? The lowest? A median? The Agreement provides no guidance, because it was never meant to cover such a scenario. Thus, if the Court accepted Esperion’s interpretation, it would need to draft new contract language from whole cloth to resolve this issue, which further illustrates that Esperion’s interpretation is not unambiguously correct.

\* \* \*

At bottom, Esperion seeks judgment on the pleadings based on an argument absent from its pleading and premised solely on two words plucked out of context from a well-established idiom. But Rule 12(c) requires that, accepting the factual assertions in DSE’s Answer as true and drawing all reasonable inferences in DSE’s favor, Esperion “establish[] that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law.” *Powermat Techs.*, 2020 WL 2892385 at \*5 (quoting *Juster*, 901 F.2d at 269). Esperion has not met that standard because it has not shown that Section 9.2 unambiguously favors its position. At best, Esperion has demonstrated that, based on the pleadings, the Agreement is ambiguous as to which relative risk reduction rate from the CLEAR Outcome Study matters for purposes of the Regulatory Milestone Payment, given that the Agreement does not define the relevant terms. But even if the pleadings show the Agreement is ambiguous as a matter of law, this is not enough to grant Esperion’s motion, because DSE has pled facts creating a plausible inference that the extrinsic evidence supports its interpretation (which Esperion does not dispute). This means that a “material issue of fact [would] remain[] to be resolved” even if the Agreement is ambiguous: whose position does the extrinsic

evidence support. *Id.* at \*5, \*7 (denying Rule 12(c) motion because “significant issues of fact [] bar judgment on the pleadings in favor of [party’s] breach of contract claim”).

### CONCLUSION

For the reasons stated above, the Court should deny Esperion’s motion for judgment on the pleadings.<sup>8</sup>

Dated: November 15, 2023  
New York New York

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<sup>8</sup> DSE does not oppose Esperion’s request for oral argument (ECF No. 76), but if the Court deems oral argument necessary DSE asks that it be scheduled on December 8 or after December 15 given the numerous depositions that the parties have scheduled between November 23 and December 15.

Certificate of Service

I hereby certify that on November 15, 2023, I caused the foregoing Opposition to Plaintiff's Motion for Judgment on the Pleadings to be filed with the Clerk of the Court and served upon all counsel of record via the Court's CM/ECF system.

/s/ Toni-Ann Citera  
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